

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD : MDL DOCKET NO. 2974
PRODUCTS LIABILITY : 1:20-md-02974-LMM
LITIGATION :
:

This document relates to: : CIVIL ACTION NO.:
Pauline Rickard : 1:21-cv-03861-LMM

ORDER - PLAINTIFF'S OMNIBUS MOTIONS IN LIMINE

1. Plaintiff's Motion to prohibit any argument, suggestion, or mention regarding the efficacy of IUDs, generally.

Plaintiff moves for the Court to exclude evidence relating to IUDs in general. Plaintiff claims that because the Paragard IUD is materially different from other IUDs available on the market in both its material and design, Defendant should not be permitted to defend Paragard using evidence of other alternative IUD products and/or designs as support.

Plaintiff argues that this evidence should be excluded under Federal Rules of Evidence 401, 402, and 403. In response, Defendant argues that Plaintiff's motion is impermissibly vague and should be denied. The Court agrees with Defendant.

Although there are certainly categories of evidence regarding other IUDs and IUDs generally that would go beyond what would be admissible, the Court cannot say that all such evidence should be excluded. In fact,

Defendant's response points to several such categories that would be potentially admissible at trial. As such, the Court **DEFERS** ruling on this issue and will address the specific evidence in the context of trial.

2. Plaintiff's Motion to prohibit any argument, suggestion, or mention that embedment is synonymous with breakage.

Plaintiff requests the Court preclude Defendants from offering testimony or evidence suggesting that embedment of Paragard is synonymous with breakage of Paragard or that the Paragard label warned of breakage outside of embedment. Specifically, Plaintiff argues that because it is uncontested that Paragard breakage can and does occur without embedment, any argument to the contrary by Defendant is prejudicial and confusing for a jury and should be excluded under Federal Rule of Evidence 403. In response, Defendant argues that it is appropriate to present evidence demonstrating that breakage can occur during removal of an embedded Paragard and that physicians knew of this risk. Defendant's response does not suggest that it would be reasonable to argue that breakage can only occur with embedment, and it appears that they agree with Plaintiff on this point.

The Court agrees with Plaintiff that embedment is not synonymous with breakage and that the evidence in this case does not support a finding that breakage only occurs with embedment. Accordingly, Plaintiff's Motion

is **GRANTED in PART** as to this issue. Defendant is not to argue that breakage can only occur with embedment.

The Court agrees with Defendant, however, that it may be relevant and not violative of Rule 403 to allow testimony that breakage can occur or generally does occur with embedment and that physicians may be aware of that risk or that the Paragard label warned of that risk. As such, Plaintiff's motion is **DEFERRED** to trial as to that issue.

3. Plaintiff's Motion to prohibit any argument, suggestion, or mention that the frequency of breakage is relevant to whether such an adverse event must be included in a product's label.

Plaintiff moves to prohibit argument that the frequency of breakage reports regarding Paragard is relevant to whether breakage as an adverse event or warning is required to be included in the Paragard label. In response, Defendant agrees that it does not intend to argue that a drug manufacturer's regulatory obligation to include an adverse event in a drug's labeling depends solely on the frequency at which the event occurs. However, they disagree as to Plaintiff's contention that frequency is not a factor in determining whether an adverse event should be included in a drug label. Both parties point to FDA guidance to support their arguments. In addition, Defendants argue that the frequency of breakage reports is admissible under Florida law because the jury must consider a number of

factors, including the likelihood/gravity of potential injury, in assessing whether Paragard's design is unreasonably dangerous.

At this stage, the Court does not find that Plaintiff has shown that all evidence of frequency of breakage reports regarding Paragard should be excluded. As such, the Court **DEFERS** ruling on this issue and will address the specific evidence in the context of trial.

4. Plaintiff's Motion to prohibit any argument, suggestion, or mention that "hormone-free" IUDs are safer than hormonal IUDs.

Plaintiff argues that Defendant has not proffered any argument or evidence in this case that hormone-free IUDs are any safer than hormonal IUDs, but, even if they had, Plaintiff claims that it would be irrelevant. In response, Defendant argues that it should be allowed to introduce evidence that the Paragard IUD is hormone-free because this feature impacted Plaintiff's reasoning for choosing the Paragard and evidence of the Paragard's safety profile would otherwise be admissible.

The Court agrees with Defendant's argument that Plaintiff's reasons for choosing the Paragard and the fact that it is non-hormonal should not be excluded, but the Court finds no evidence supporting any argument that hormone-free IUDs are safer than hormonal IUDs. Absent some sort of support for that conclusion, the Court **GRANTS in PART** Plaintiff's Motion. Defendant may inquire as to why Plaintiff chose the Paragard IUD

and introduce evidence that it is non-hormonal, but Defendant is prohibited from arguing that a non-hormonal IUD is safer absent some sort of admissible evidence in support.

5. Plaintiff's Motion to prohibit any argument, suggestion, or mention that Plaintiffs are attempting to limit the availability of birth control to women.

Plaintiff contends that Defendant should be precluded from advancing any argument that Plaintiff's Counsel is attempting to limit the availability of birth control to women. Plaintiff argues that such an argument is entirely irrelevant to Plaintiff's claims, and the risk of undue prejudice to Plaintiff substantially outweighs any probative value. Fed. R. Evid. 401, 403.

In response, Defendant agrees not to argue that a verdict for Plaintiff would result in Paragard becoming unavailable to women or being withdrawn from the market. Defendant further responds that the motion should not be construed more broadly to exclude evidence regarding the role Paragard plays as a non-hormonal contraceptive option. Because the Court has already ruled in response to the prior motion in limine that certain evidence relating to the non-hormonal qualities of the Paragard IUD is not excluded and the Court also construes this motion to be limited to the agreed upon issue, this Motion is **GRANTED** as agreed upon.

6. Plaintiff's Motion to prohibit any argument, suggestion, or mention that a corporate witness used or uses Paragard.

Plaintiff seeks to exclude evidence as to whether an employee or other corporate witness has used or uses Paragard as wholly irrelevant to Plaintiff's claims at issue. Plaintiff further argues that such testimony or evidence would only serve to distract the jury from fairly evaluating Plaintiff's claims and injuries and would be unduly prejudicial to Plaintiff. In response, Defendant argues that such a motion is premature, and the evidence is highly relevant to disputed issues in this case, including basic witness credibility as well as Plaintiff's punitive damages allegation that Defendant acted with malice and reckless disregard for safety.

The Court agrees with Plaintiff. Even though there may be some relevance as to whether individuals or their sexual partners may personally choose a Paragard IUD for birth control, the Court finds that this evidence should be excluded under Rule 403. There are many personal reasons for choosing a birth control option. Allowing witnesses to be questioned or cross-examined on this highly personal and fact-intensive decision would result in causing unfair prejudice, confusing the issues, misleading the jury, causing undue delay, and wasting time in a way that substantially outweighs its probative value. Accordingly, this Motion is **GRANTED** for all witnesses except for Plaintiff.

7. Plaintiff's Motion to prohibit any argument, suggestion, or mention of attorney advertising.

Plaintiff argues that attorney advertising related to this litigation is entirely irrelevant to Plaintiff Rickard's case, and any mention of it by Defendant could create a distraction from the issues of the case, thus prejudicing Plaintiff. In response, Defendant argues that attorney advertising is relevant to question potential jurors in voir dire regarding what they have heard about the case and in evaluating the reasons behind a recent spike in Paragard breakage reports, which may be attributable to attorney advertising.

As to voir dire, the Court will review the parties' requested voir dire questions and will rule on whether a question about attorney advertising is permissible as part of that effort. As to whether attorney advertising might be driving a spike in breakage reports, the Court will not exclude that evidence at this time. As such, the Court **DEFERS** ruling on this motion in the context of trial. If Defendant attempts to introduce evidence relating to attorney advertising in another context, they are to approach the bench before doing so.

9. Plaintiff's Motion to prohibit any argument, suggestion, or mention as to how, when, or under what circumstances Plaintiffs chose or employed their attorneys, including any referral arrangements or other counsel that Plaintiff may have retained other than her current counsel.

Plaintiff moves to exclude how, when, or under what circumstances Plaintiffs chose or employed their attorneys as irrelevant to the issues in this litigation. During the hearing on this motion, the parties reached an agreement as to this issue. Defendant will be allowed to cross-examine Plaintiff on potential inconsistencies on her Paragard timeline, but Defendant will not inquire as to these attorney-specific issues. As such, this Motion is **GRANTED** as agreed upon.

8. Plaintiff's Motion to prohibit any argument, suggestion, or mention that the volume of adverse events or adverse drug reactions for other products—not Paragard—is relevant to the safety profile of Paragard.

Plaintiff contends that whether and to what extent other IUD products cause adverse events and/or injuries like the injuries claimed by Plaintiff is wholly irrelevant to the disputed issues. Under Federal Rule of Evidence 401 and 403, Plaintiff alleges that such testimony or evidence should be excluded, as its relevance is lacking, and the risk of confusing the issues and misleading the jury outweighs any probative value. In response, Defendant first argues that Plaintiff's motion is vague and overbroad. Defendant then argues that such evidence could be admissible as to the defect claims.

Although there are certainly categories of evidence regarding other IUDs that would go beyond what would be admissible, the Court cannot say that all such evidence should be excluded. In fact, Defendant's response points to several such categories that would be potentially admissible at trial. As such, the Court **DEFERS** ruling on this issue and will address the specific evidence in the context of trial.

9. Plaintiff's Motion to prohibit any argument, suggestion, or mention that physicians knew about the undisclosed risk of breakage upon removal because it is an inherent risk with all IUDs.

Plaintiff argues that general, unverifiable hearsay statements, speculation, and/or unsupported opinions from fact, corporate, or defense expert witnesses that the risks of breakage with Paragard would be generally known to physicians, are based on pure speculation, wholly irrelevant to the questions to be decided by the jury, and extremely prejudicial. Plaintiff further contends that the assertion of the extent of the medical community's knowledge of Paragard's propensity to break does not negate or alter Defendant's duty to warn of the known risks associated with the Paragard because Defendant had a duty to warn of all material risks regardless of whether they were known by the medical community.

In response, Defendant argues that Plaintiff does not point to any examples of evidence she seeks to exclude such that her Motion is

premature and vague. Defendant then argues that such evidence could be admissible as to the defect and warning claims.

Although there are certainly categories of evidence regarding what other physicians may have known that lack foundation and may be inadmissible, the Court cannot say that all such evidence should be excluded. In fact, Defendant's response points to several such categories that would be potentially admissible at trial. As such, the Court **DEFERS** ruling on this issue and will address the specific evidence in the context of trial.

10. Plaintiff's Motion to prohibit fact testimony inconsistent with factual admissions in Defendant's 30(b)(6) testimony.

Plaintiff argues that Defendant should be precluded from introducing any evidence or testimony that contradicts Defendant's 30(b)(6) admissions. In response, Defendant argues that it is premature to rule on this motion without an understanding of what specific evidence is at issue. Defendant also disagrees with the underlying argument from Plaintiff on how 30(b)(6) testimony is to be treated at trial.

The Court agrees with Defendant that this issue is premature to address. The Court prefers to have a more concrete basis for addressing such testimony in the context of trial, as the Court may exclude certain testimony as inconsistent with a 30(b)(6) deponent but potentially allow other testimony to be handled by cross-examination. This could depend on

the actual testimony and degree of contradiction. As such, Plaintiff's Motion is **DEFERRED** until the context of trial.

11. Plaintiff's Motion to prohibit Defendant from affirmatively introducing or designating Fed. R. Civ. P. 30(b)(6) deposition testimony.

Plaintiff argues that Defendant should be excluded from introducing or designating any 30(b)(6) deposition testimony at trial based on Federal Rule of Civil Procedure 32's statement that a corporate witness' deposition may be used only by an adverse party. Although the Court generally agrees with Plaintiff's interpretation of the Federal Rules of Civil Procedure, the Court understands that certain 30(b)(6) deposition testimony may be designated for trial under Rule 32(a)(6) for completeness. As such, the Court **DEFERS** ruling on this issue until objections to deposition designations are ruled upon.

12. Plaintiff's Motion to prohibit any argument, suggestion, or mention that the FDA shared responsibility for the Paragard label and/or that Defendants and the FDA were in a partnership on the Paragard label.

Plaintiff argues that because a drug manufacturer alone has ultimate responsibility for a product's label, Defendant should be prohibited from arguing or asserting that the FDA shares ownership responsibility for the ultimate content and language of the label. In narrowing its motion, Plaintiff makes clear that it does not oppose Defendant arguing that the

FDA approved Paragard's label or ultimately approved any label changes submitted via Prior Approval Supplement or Changes Being Effected ("CBE") pathway. Instead, Plaintiff primarily takes issue with any suggestion by Defendant that the FDA has shared ownership responsibility for the label's content and information or that the FDA could have made changes to the label without notice to and input from Defendant. In response, Defendant argues that granting Plaintiff's motion would impermissibly narrow the FDA's role in approving and initiating drug labels.

As explained in the Court's order on preemption, the CBE pathway was open to Defendant to initiate a change to its label. This could have been done without the FDA initiating the change, but the change would still have been subjected to FDA oversight. In addition, when the Paragard was originally approved for sale, the FDA also approved its label. The Court will not exclude these factual representations or reasonable arguments based on these concepts. To the extent that Defendant wants to relitigate the preemption issue, the Court will not allow that to be done in front of the jury. Otherwise, the Court will have to view specific representations in the context of trial because it is unclear what exact evidence Plaintiff seeks to exclude and how Defendant may introduce it at trial. As such, the Motion is **DEFERRED** until the context of trial.

13. Plaintiff's Motion to prohibit any argument, suggestion, or mention that the FDA's approval of the Paragard label is proof of legal adequacy or a safety determination.

Plaintiff argues that Defendant should be precluded from offering any testimony or argument that suggests that because the FDA approved Paragard at its inception, its safety has been definitively established for now and forever. In response, Defendant agrees that it has no intention to argue that FDA approval is legally dispositive. Because Defendant has agreed not to make this argument, Plaintiff's Motion is **GRANTED** as agreed upon. Defendant will not argue that the FDA's initial approval of its drug absolves it from responsibility or ultimately determines the defect and warnings issues in this case. Defendant is entitled to explain how Paragard—and its labeling—were approved by the FDA for distribution in the United States.

14. Plaintiff's Motion to prohibit any argument, suggestion, or mention that FDA silence or inaction is evidence of the adequacy of the Paragard label.

Plaintiff argues that Defendant should be precluded from arguing or suggesting to the jury that FDA inaction or silence as to the lack of a specific warning or adverse reaction is indicative of the adequacy of the Paragard label regarding its safety. In response, Defendant agrees that it does not intend to argue that the FDA's silence or inaction as to a particular issue is legally dispositive of the adequacy of a manufacturer's conduct.

Defendant does, however, dispute that the FDA's silence or the absence of enforcement activity is irrelevant and inadmissible.

Because Defendant has agreed not to make part of the argument to which Plaintiff objects, Plaintiff's Motion is **GRANTED in PART** as agreed upon on this issue. Defendant will not argue that FDA's silence or inaction as to a particular issue is legally dispositive of the adequacy of a manufacturer's conduct. As to the additional issue as to whether this evidence is admissible as to adequacy, the Court **DEFERS** ruling on this as to the specific evidence in the context of trial.

15. Plaintiff's Motion to prohibit any argument, suggestion, or mention that Defendant could not change Paragard's label while label change negotiations were ongoing with FDA.

Plaintiff argues that it would be disingenuous for Defendants to suggest that they could not file a CBE submission adding breakage to the Paragard label during label negotiations with the FDA. In response, Defendant does not contend that FDA regulations impose a categorical legal bar to any labeling change whenever "negotiations were ongoing with FDA." Defendant further objects to a wider reading of Plaintiff's Motion. Because Plaintiff's Motion only narrowly addresses the situation of label negotiations to which Defendant agrees, Plaintiff's Motion is **GRANTED** as agreed upon. Defendant is prohibited from arguing that FDA label negotiations alone prevented it from changing the Paragard label.

16. Plaintiff's Motion to prohibit any argument, suggestion, or mention that federal law prevented Defendants from strengthening Paragard warnings.

Plaintiff moves to prevent Defendant from arguing that federal law preempted them from strengthening the Paragard label regarding warnings. As explained in the Order on Plaintiff's Motion in Limine 11 and the Court's Order on preemption, the CBE pathway was open to Defendant to initiate a change to its label. This could have been done without the FDA initiating the change, but the change would still have been subjected to FDA oversight. In addition, when the Paragard was originally approved for sale, the FDA also approved its label. The Court will not exclude these factual representations or reasonable arguments based on these concepts. To the extent that Defendant wants to relitigate the preemption issue, the Court will not allow that to be done in front of the jury. Otherwise, the Court will have to view specific representations in the context of trial because it is unclear what exact evidence Plaintiff seeks to exclude and how Defendant may introduce it at trial. As such, the Motion is **DEFERRED** until the context of trial.

17. Plaintiff's Motion to prohibit argument regarding the FDA's approval of the 2005 label.

Plaintiff moves to exclude any evidence or arguments put forth by Defendant regarding the FDA's approval of the 2005 Paragard label,

including but not limited to communications with the FDA regarding the approval of the 2005 label. In support of her motion, Plaintiff recites the history of the 2005 label and Defendant's failure to timely update it. Plaintiff argues that how, or why, the FDA approved a label under a different set of regulations is entirely irrelevant to whether that label was adequate at the time of Plaintiff's implant. Plaintiff further argues that such argument is false, misleading, and should be excluded under a Rule 403 balancing test.

In response, Defendant provides its own version of the FDA timeline and history of the 2005 label, including the fact that this label was approved by the FDA. Defendant argues that the history and context of Paragard's labeling and history is relevant evidence for the jury.

The Court agrees with Defendant. However, consistent with the Court's other rulings on FDA approval and preemption, Defendant cannot use the FDA approval process inappropriately. Both sides should be allowed to provide the jury with the complete context and history of the Paragard label. As such, Plaintiff's Motion is **DEFERRED** until the specific evidence is viewed in the context of trial.

18. Plaintiff's Motion to prohibit any argument, suggestion, or mention that obesity played a role in Mr. Rickard's Paragard breakage.

Plaintiff argues that any role her obesity may have played in her Paragard breakage should be excluded. In response, she cites to the testimony of Ms. Rickard's treating physician expressly denying that obesity played a role in her breakage. *See, e.g.*, Deposition of Niloufer Kero, M.D. (3/25/2025) at 106:14-19 (testifying that Ms. Rickard's obesity did not "cause any implications with the removal of her Paragard."). In opposition, Defendant cites to a more general statement from this same witness explaining that obesity, in some circumstances, increases the chance of complications because it may make visualization of the cervix more difficult. Kero Dep. 85:21-25, 59:2-11.

Although Dr. Kero testifies that obesity can impact removal, it is important that she testified that it did not impact removal in this case. Defendant points to no other witness who will testify that Plaintiff's obesity played a role in her Paragard breakage. Consequently, the Court agrees with Plaintiff and will exclude her diagnosis of obesity as not probative on the issue of breakage. *See Fed. R. Evid. 401, 403.* Plaintiff's Motion on this issue is **GRANTED**.

19. Plaintiff's Motion to prohibit any argument, suggestion, or mention that Ms. Rickard's Paragard improved her polycystic ovarian syndrome ("PCOS") symptoms or that her pain post-removal is due exclusively to PCOS.

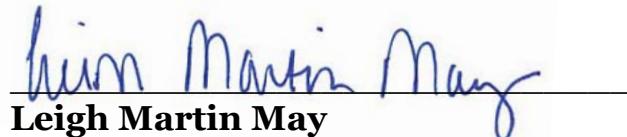
Plaintiff argues that Defendant should be excluded from offering any testimony or suggestion that her Paragard improved her PCOS symptoms or that Plaintiff's pain post-removal of Paragard is wholly due to her PCOS. Plaintiff contends that such testimony is plainly irrelevant to Plaintiff's injuries and would serve as nothing more than a confusion tactic diverting attention from the crux of the issue in this case. Fed. R. Evid 401, 402, 403. In support of her argument, Plaintiff asserts that her diagnosis occurred years prior to the date she had Paragard placed and that prior to her Paragard placement in 2012, she had not experienced significant pain from her PCOS. In response, Defendant argues that such testimony is highly relevant. Defendant references Dr. Horvath's expert testimony indicating that some of the damages Plaintiff claims may have been caused by her PCOS.

The Court agrees with Defendant and finds that this information should not be excluded at this time. It appears that there may be some relevance to Plaintiff's PCOS diagnosis as to her damages. As such, Plaintiff's Motion is **DEFERRED** until the context of such evidence is introduced at trial.

20. Plaintiff's Motion to prohibit any fact and/or expert testimony or other evidence that Ms. Rickard's physicians were at fault for the Paragard breaking during either the implant or removal procedures.

As the parties have reached an agreement on this issue by stipulation, the Court adopts the stipulation. The Motion is hereby **DENIED** as moot.

IT IS SO ORDERED this 5th day of January, 2026.


Leigh Martin May
Chief United States District Judge